Remarks

Status of the Claims

The Office objected to Claims 6 and 19 as identical to other claims.

The Office objected to Claim 28 due to a misspelling.

The Office rejected Claims 7 and 20 under 35 U.S.C. 112 as indefinite.

The Office rejected Claims 1-7, 10-20, and 23-29 under 35 U.S.C. 102 as anticipated by U.S. Patent 5,885,212 (*Scharlack*).

The Office rejected Claim 27 under 35 U.S.C. 102 as anticipated by U.S. Patent Application Publication number US 2003/0109772 (*Mills*).

The Office indicated that Claims 8-9 and 21-22 would be allowable if rewritten in independent form, including all the limitations of the base and any intervening claims.

In this Response, Applicant:
Traverses the rejections of Claim 1, 10, 11, 14, and 23, and amends Claim 14 to clarify an antecedent;
Cancels redundant Claims 6 and 19;
Rewrites Claims 7 and 20 in independent form responsive to the Office's indication of allowability of Claims 8-9 and 21-22;
Cancels Claims 27 and 29;
Amends Claim 28 to cure the rejection under 35 U.S.C. 112.

Claims 7-9 and 20-22

The Office indicated that Claims 8-9 and 21-22 would be allowable if rewritten in independent form, including all the limitations of the base and any intervening claims, in part since the wavelength range in those claims was not taught by *Scharlack*. The wavelength range taught by *Scharlack* as applicable extends only to 900nm (11,111cm-1). Accordingly, Applicant submits that the limitation in amended Claims 7 and 20 to wavelengths in the range from 4000 to 11,000cm-1 is not taught by *Scharlack*, and that Claims 7 and 20 are in condition for allowance. Claims 8-9 and 21-22 have been amended to depend from Claims 7 and 20 respectively, and Applicant submits that they are also now in condition for allowance.

Claim 28

Applicant has rewritten Claim 28 in independent form, including all and only the limitations of original parent Claim 27. Applicant has amended Claim 28 to remove the characterization of the radiation as "infrared" to remove the possible confusion with the specific wavelength regions recited. Applicant has amended Claim 28 to correct the misspelling noted by the Office.

Claim 28 includes the limitation that pH be determined using radiation in the frequency range from 4000 to 10,000cm-1. As discussed and noted by the Office in connection with Claims 8-9 and 21-22, the art does not teach or suggest the use of that wavelength region in the determination of pH according to the method of the claimed invention. Accordingly, Applicant submits that Claim 28 is in condition for allowance.

Claims 1-5 and 10-13, and Claim 14-18 and 23-26

The Office rejected Claim 1-5, 10-13, 14-18, and 23-26 under 35 U.S.C. 102 as anticipated by *Scharlack*. Applicant respectfully traverses this rejection, because *Scharlack* does not teach two limitations recited in Claim 1.

The methods of Claims 1 and 14 have the limitation of a step of determining the concentration of hemoglobin in the sample. The Office suggested that *Scharlack* taught this limitation. *Scharlack* column 5 lines 18-38. Applicant submits that this characterization of *Scharlack* is incorrect. *Scharlack* determines pH vectors for hemoglobin fractions, not hemoglobin concentration. *Scharlack* column 5 lines 18-38. *Scharlack's* pH vectors comprise the difference in absorbance of a hemoglobin fraction are two different pH levels. *Scharlack* column 5 lines 33-35. These vectors,

representing absorbance differences, can then be combined in various ways. *Scharlack* does not teach determination of the concentration of hemoglobin, as required in Claims 1 and 14. Accordingly, *Scharlack* does not teach all the limitations of Claims 1 and 14, and there is no pri*ma facie* case of anticipation.

Further, the methods of Claims 1 and 14 have the limitation of a step that selects a model that is applicable for samples having the determined hemoglobin concentration. *Sharlack* has no teaching of such a step, not surprising since *Scharlack* does not determine hemoglobin concentration. *Scharlack* has a single model that is cognizant of the pH vectors, and accordingly has no need for determination of hemoglobin concentration, and no need (or teaching) of selection of a model applicable to samples with specific hemoglobin concentrations. Accordingly, *Scharlack* does not teach all the limitations of Claims 1 and 14, and there is no *prima facie* case of anticipation. Applicant submits that Claims 1 and 14, and Claims 2-5, 10-13, 15-18, and 23-26 depending therefrom, are in condition for allowance.

Claims 10 and 23

As discussed above, *Scharlack* does not teach all the limitations of parent Claims 1 and 14. Claims 10 and 23 further recite the limitation to spectral measurements at resolutions of 64cm-1 or finer. *Scharlack* does not teach this resolution. Accordingly, *Scharlack* does not teach or suggest all the limitations of Claims 10 and 23, and there is no *prima facie* case of anticipation. Applicant submits that, even if the parent claims were anticipated by *Scharlack*, Claims 10 and 23 are allowable.

Claims 11 and 24

Applicant has amended Claims 11 and 24 to remove the alternative of noninvasive measurement of perfused tissue. Applicant's invention allows the user of hemoglobin concentration determined in any manner; specifically, in Claims 11 and 24, determined by measurement of blood samples. The hemoglobin concentration can then be used to improve the performance of spectroscopic pH determinations. *Scharlack* does not teach measurement of hemoglobin concentration, and consequently does not teach the use of hemoglobin concentrations determined from blood samples and used in connection with a spectroscopic determination of pH. Accordingly, *Scharlack* does not teach all the limitations of Claims 11 and 24, and there is no *prima facie* case of anticipation. Applicant submits that, even if the parent claims were anticipated by *Scharlack*, Claims 11 and 24 are allowable.

Conclusion

Applicant has responded to each and every rejection and urges that the Claims as presented are in condition for allowance. Applicant requests expeditious processing to issuance.

Respectfully submitted,

/V. Gerald Grafe/ Dec. 7, 2004

V. Gerald Grafe — date

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I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited on the date shown below with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents; P.O. Box 1450; Alexandria VA 22313-1450.

Dec 7, 2004 — date

/V. Gerald Grafe/ — name